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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,789

09/23/2003

Yong D. Zhao

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EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

12/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,789	Applicant(s) ZHAO ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2006 has been entered.

Election/Restrictions

Newly amended claims 9-16 and 24-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions I (claims 1-8 and 17-23) and Inventions II (claims 9-16 and 24-30) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs. Invention II recites the additional structure of a second taper zone and a separator zone between the first and second taper zones. Conversely, invention I does not require a second tapered zone, and thus does also not have a separator zone.

Since applicant has received an action on the merits for the originally presented invention (invention I), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

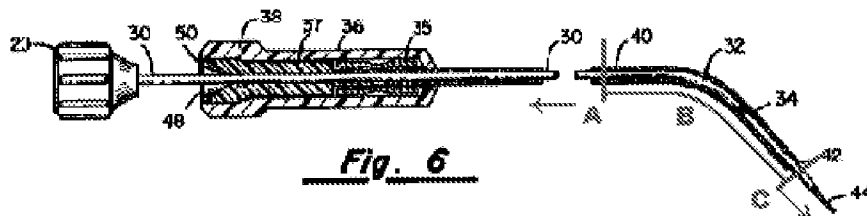
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 8 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013). Dutcher discloses a taper zone extending within the curved intermediate segment. Furthermore, Dutcher in figure 6 displays a two-piece stylet in a “J” shape (please see below).



The examiner considers the claimed substantially straight proximal segment to be from the proximal end to point A, the curved intermediate segment is defined by segment B (between points A and C) and point C to the tip is considered to be the substantially straight distal segment.

As displayed above in the replica of figure 6, the taper zone, originates in the curved section and decreases or tapers, such as at point 42 and further in the

substantially straight distal segment beyond point C. Therefore, Dutcher does disclose a taper zone extending from within the curved intermediate segment.

It is further noted that the claim does not state that the taper is in a curved portion of the curved segment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 5-7 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher (US 4,381,013) in view of Hartley et al. (US 20040073141 A1). Since Dutcher does disclose a tapered zone extending within the curved intermediate segment, the arguments in regards to claims 5-7, 13-15, 21-23 and 28-30 are considered moot.

Dutcher discloses the claimed invention except for the degree of the curve being approximately 180 degrees, approximately 210 degrees or some value therebetween. Hartley et al. teaches that it is known to use a curve in the range of 140 to 200 degrees

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as set forth on page 4, paragraph 68 for navigating within the heart with minimizing damage and irritation to the aortic heart valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the curvature as taught by Dutcher with the degree of curvature as taught by Hartley et al., since such a modification would minimize trauma to the vasculature.

As to claims 5, 7, 21 and 23, the examiner considers 200 degrees to be approximately 210 degrees.

2. Claims 1-8 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 4,498,482). Williams disclose a tapered stylet for assisting in the placement of a pacing lead as seen in figures 1-3 and 5. However, Williams does not disclose a preformed j-shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stylet of Williams with a j-shaped stylet in order to yield the predictable results of reducing trauma to the arterial system.

As to claims 1 and 17, the well known construction of a j-shape is with a substantially straight distal segment, a curved intermediate segment and a substantially straight distal segment.

As to claims 5-7 and 21-23, the modified Williams discloses the claimed invention except for the specific degree of curvature within the curved segment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the degree of curvature to yield the predictable results of optimizing the degree of curvature, since it has been held that where the general conditions of a claim

are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

As to claim 8, the modified Williams discloses the claimed invention except for the extendable/retractable helix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead system with a fixation device, specifically an extendable/retractable helix, to provide the predictable results of engaging the lead into the tissue to maintain intended positioning. Furthermore, the employment of such extendable/retractable helixes is well known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/George R Evanisko/
Primary Examiner, Art Unit 3762

Alyssa M Alter
Examiner
Art Unit 3762